

ENCLOSURES FOR

EPA-HQ-2018-001919
J. Benton Hurst, Esq.

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Glyphosate **Duffy, Rick** From: Sent: Tuesday, March 17, 2015 8:46 AM To: Subject: FW: GLP Certification Attachments: image001.jpg Importance: High Do you need anything from me for the MAMPD General with Betsy when the e-mail from Cynthia is discussed? EXG Sent: Tuesday, March 17, 2015 7:45 AM Subject: FW: GLP Certification Hi 🖠 EX6 Got your email on this. I suggest we wait on preparing a response until Ed speaks with Betsy and others. TX6 ExG Sent: Monday, March 16, 2015 9:18 PM Subject: Fwd: GLP Certification Fyi you mentioned something about this to me. Sent from my iPhone Begin forwarded message: Date: March 16, 2015 at 6:58:57 PM EDT To: , "Duffy, Rick" < Duffy.Rick@epa.gov>, 🗗 🗶 👂 EXL Cc: " EXL Subject: FW: GLP Certification

Please add this to your weekly this week. We should also plan on circling back to Cynthia next week or by email.

From: Giles-AA, Cynthia

Sent: Monday. March 16, 2015 5:54 PM

To: Cc:

Subject: FW: GLP Certification

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S-AA, Cynthia Exc	
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Best regards



- Repeated Dose Toxicology
- Reproductive/Developmental Toxicology
- Genetic Toxicol
- Environmental Toxicology
- Product Chemistry

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- GLP Analytical Chemistry
- Antimicrobial Efficacy

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From: Eメし Sent: Saturday, February 28, 2015 6:55 AM



Subject: GLP Certification

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- Repeated Dose Toxicology
- Reproductive/Developmental Toxicology
- Genetic Toxicology
- Environmental Toxicology
- Product Chemistry
- GLP Analytical Chemistry
- Antimicrobial Efficacy

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Yours sincerely,

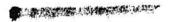
Market®istration Division

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Best regards



- Repeated Dose Toxicology
- Reproductive/Developmental Toxicology
- Genetic Toxicology
- Environmental Toxicology
- Product Chemistry
- GLP Analytical Chemistry
- Antimicrobial Efficacy



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From: Giles-AA, Cynthia Sent: Monday, March 16, 2015 5:54 PM To: Cc: Subject: FW: GLP Certification	
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Sent: Monday, March 16, 2015 10:29 AM To: Exb Subject: RE: GLP Certification	
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Sent: Saturday, February 28, 2015 6:55 AM

To: @Epa.gov' EX/
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Market®istration Division

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Best regards



- Repeated Dose Toxicology
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Subject: GLP Certification	
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Duffy, Rick		
From: Sent: To:	Thursday, March 19, 2015 9:01 AM	
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For your review, com	ent and/or approval, attached you will find:	
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U.S. EPA 1200 Pennsylvania Ave., N.W. Washington, DC 20460

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Draft Response to Incoming Email: Dear Mr. Your email to has been forwarded to me for response. As ndicated in mail to > Exc vou. As such, I sincerely appreciate receiving feedback from members of the GLP community and recognize the issues and concerns raised in your email. I understand your frustration. However, I want to assure you that EPA is not resisting the issuance of GLP certificates, as you indicate in your email. As currently written, recent Fungicide and Rodenticide Act nor the Good Laboratory Practice regulations authorize the issuance of certifications. The GLP program is based on existing statutory and regulatory authorities, authorize a compliance monitoring and enforcement program to detect and deter violations of the regulations and to assist in regulatory decision-making. EPA's inspection program is accepted by OECD and, therefore, we do participate in the Mutual Acceptance of Data program. If you would like to discuss your concerns or if you have any questions about EPA's GLP program, a teleconference can be arranged. Sincerely, Incoming: Sent: Monday, March 16, 2015 2:51 PM EXP Giles-AA, Cynthia Ex6 Subject: RE: GLP Certification I am forwarded your message to my colleague in the has responsibility for the issue you have raised. Thanks. From: EX6 Sent: Monday, March 16, 2015 10:29 AM P EXL Subject: RE: GLP Certification I never heard back from you about this. Can we please schedule a time to sp

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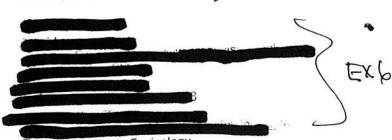
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I have been with Product Safety Labs for over 25 years and have grown incredibly frustrated over this issue. I would like to know if you could be available for a short discussion by phone so that I could understand the agencies position on this issue and discuss possible ways to address it.

Best regards



- Repeated Dose Toxicology
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- Genetic Toxicology
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Briefing for Cynthia Giles

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Best regards



Quick Response:

Currently, neither FIFRA nor the Good Laboratory Practice Regulations authorize the issuance of certifications. The existing GLP inspection program constitutes a compliance monitoring and enforcement program to detect and deter violations of the GLP regulations and to assist in regulatory decision-making.

Ex6= Exemption &

Overview of the Current FIFRA GLP Program

EPA's GLP Program is a quality management system used to ensure the integrity and validity of scientific studies and data generated and submitted as part of pesticide or chemical under FIFRA. EPA does not test pesticides to support registrations. Rather, EPA relies on studies performed by or for applicants for registration. Laboratories are sometimes owned by the registrant but can also be independently operated and hired by the registrant. It is not required for the laboratory to be certified, however, studies that are submitted to EPA in support of registration applications must be conducted in accordance with the GLP regulations, which requires laboratory personnel to have adequate education, training and experience to conduct the study.

The GLP regulation, 40 CFR Part 160, covers a wide variety of areas including equipment maintenance and calibration, testing operations, test substances, study protocols, the conduct of a study, recordkeeping and reporting requirements as well as testing facility management of the GLP regulation is the Statement of compliance or non-compliance. 40 CFR 160.12. Any person who submits an application to EPA for a research or marketing permit that contains a study must submit a true and correct statement, signed by the applicant, the sponsor of the study and the study director. The statement must contain one of three listed assertions: (1) whether the study was conducted in accordance with GLP rule or (2) all the differences between the practices used in the study and those required by the GLP rule or (3) the signatory was not a sponsor or the study, did not conduct the study and does not know whether the study was conducted in accordance with the

An NAIS inspection will include an on-site facility compliance review as well as a data audit. A data audit is where a study is selected and reviewed by the inspection of the study is consistent with the final report that was submitted to EPA. The NAIS uses a random selection process or the Laboratory Information and Study Audit (LISA) database that screens for the following neutral criteria:

- Labs that have submitted the most number of studies to EPA in the last syears.
- Labs that had major GLP findings in a previous inspection,
- Labs that have initiated testing under FIFRA or TSCA for the first t
- Labs that have submitted a study that is expected to form the bas action,
- Labs that have not been inspected for the last 3 years,
- Labs located in geographic proximity to other laboratories.

Currently, the only sections of FIFRA that would address violations of the GLP regulations is FIFRA Section 12(a)(2)(M)(Q) and (R). All are based on submissions to the Agency. The most common enforcement action concerns the submission of a false 160.12 compliance statement where the submitter attests that a study was conducted in accordance with GLP regulations, but deviations were found during the inspections. If this statement is false, a civil or criminal enforcement response may be

pursued by the Agency. There are no other bases for initiating an enforcement action for a violation of the GLP regulations. In the case of missing raw data, an enforcement action can be initiated for violating 40 CFR Part 169. GLP violations can result in the rejection of a study by EPA and, therefore, a denial of a registration application.

The GLP Program is affected by EPA's membership in the Organization for Economic Cooperation and Development (OECD). As an OECD member, EPA subscribes to the Mutual Acceptance of Data (MAD) program. The MAD program requires OECD members to accept data from each other for review. This program benefits the United States economy by making it easier for pesticide and chemical companies to engage in international trade. To be part of the MAD program, EPA must have a valid and active GLP Compliance Monitoring Program and conduct inspections. A certification program is not required.

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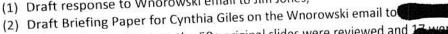
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Duffy, Rick	.5	8
From: Sent: To:	Monday, March 23, 2015 1:30 PM	
Subject:	Duffy, Rick TX 6	
Attachments:	response.docx; Briefing for Letter.Briefing for Cynthia Giles.docx	
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1200 Pennsylvania Ave Washington, DC 20460		
From:	EXP	
Sent: Monday, March 2		
To: f Subject: FW: From Wee	ekly	
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JAP GAP		
Here is the incoming let	ter and our proposed response for your approval.	
From:	EX	
Sent: Friday, March 20,	2015 10:53 AM	
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From: Sent: Thursday, March 1 To: Subject: FW: From Weel	Duffy, Rick EX	
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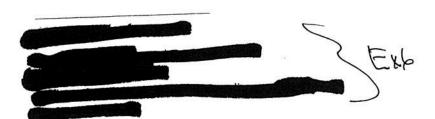
EX6 = Exemption

(1) Draft response to Wnorowski email to Jim Jones,



(3) Slides – At your request, the 50+ original slides were reviewed and 12 were selected to fit the time allotment for the briefing.

Exp



EXP Fron

Sent: Wednesday, March 18, 2015 5:41 PM

ELP Cc: Duffy, Rick

Subject: From Weekly

Prepare response to lab letter on GLP certifications.

Put on weekly for next week with Cynthia.

Finish GLP slides for Cynthia asap.

Tx.

U.S. EPA

1200 Pennsylvania Ave., N.W. (MC-2227A)

Washington, DC 20460

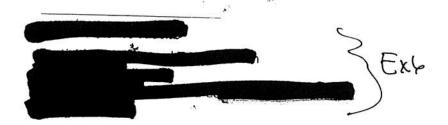
Excuption &

From: Sent: To: Subject: Attachments: Please see my comments on the email response. Let me know if anything is not accurate. From: Sent: Trom: Duffy, Rick Friday, March 27, 2015 3:05 PM Duffy, Rick RE: From Weekly Please see my comments on the email response. Let me know if anything is not accurate. From: Sent: Thursday, March 19, 2015 9:01 AM To: Duffy, Rick

For your review, comment and/or approval, attached you will find:

Subject: FW: From Weekly

- (1) Draft response to Wnorowski email to
- (2) Draft Briefing Paper for Cynthia Giles on the Wnorowski email to Jim Jones,
 - (3) Slides At your request, the 50+ original slides were reviewed and 17 were selected to fit the time allotment for the briefing.

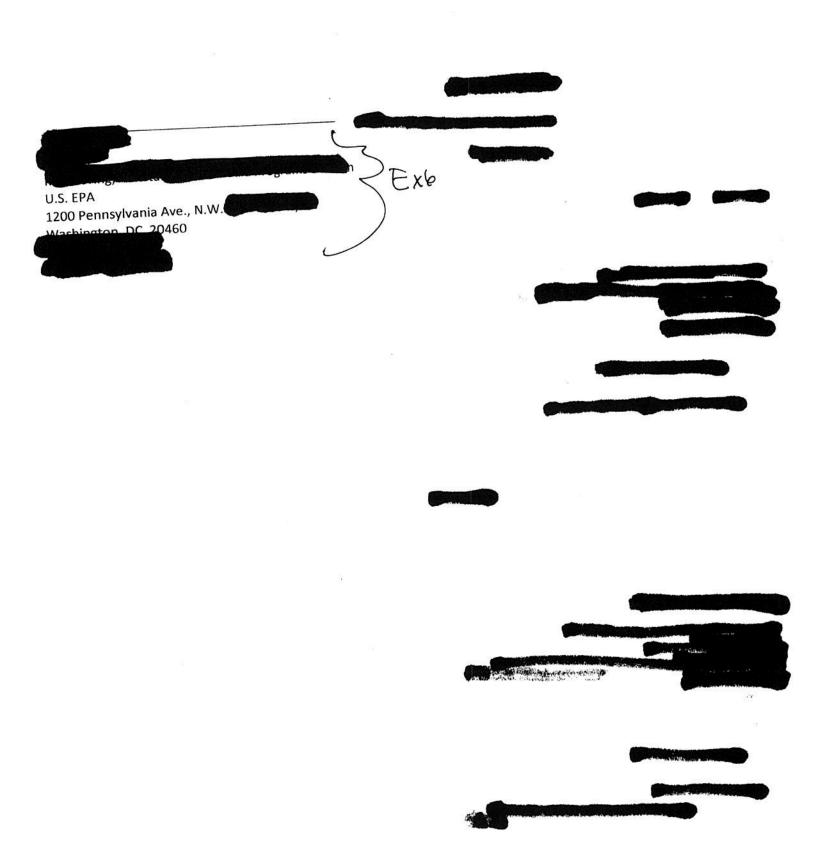


Sent: Wednesday, March 18, 2015 5:41 PM
To
Cc: Duffy, Rick
Subject: From Weekly

Prepare response to lab letter on GLP certifications. Put on weekly for next week with Cynthia. Finish GLP slides for Cynthia asap.

Exe = Exemption 6

Tx.



EX6= Exemption b

Draft Response to Incoming Email: Your email to has been forwarded to me for response. As EX6 As such, I sincerely appreciate receiving teedback from members of the GLP community and recognize the issues and concerns raised in your email. Lunderstand your frustration. Lunderstand your frustration. However, I want to assure you that EPA is not resisting the issuance of GLP certificates, as you indicate in your email. As currently written, neither the Federal Insecticide, Fungicide and Rodenticide Acturor the Good Laboratory Practice regulations authorize the EPA to certify Constitution and Provided the EPA to certify Constitution and Provided the EPA in the Institution of Constitution and Provided the EPA in the Institution of Constitution and Provided the EPA in the Institution of Constitution and Provided the Institution of Constitution and Provided the Institution of Constitution of Constit support of registration applications must be conducted in accordance with the GLP regulations, which ifes laboratory personnel to have adequate education, training and experience to conduct the study. A change in this framework will require changing the regulations. The GLP program is based on existing statutory and regulatory authorities, which authorize a compliance monitoring and enforcement program to detect and deter violations of the regulations and to assist in regulatory decision-making. EPA's inspection program is accepted by OECD and, therefore, we do participate in the Mutual Acceptance of Data and a If you would like to discuss your concerns or if you have any questions about EPA's GLP program, a teleconference can be arranged. Sincerely, Incoming: From: Sent: Monday. March 16, 2015 2:51 To: Subject: RE: GLP Certification am forwarded your message to my colleague in the Office of Enforcement and Compliance Assurance, Frances Liem. She has responsibility for the issue you have raised. Thanks. Jim From: Sent: Monday, March 16, 2015 10:29 AM Subject: RE: GLP Certification EXF

I never heard back from you about this. Can we please schedule a time to speak this week? EXP Sent: Saturday, February 28, 2015 6:55 AM Subject: UL -I manage a contract lab that specializes in the conduct of toxicology and chemistry studies on pesticides for submission to global regulatory authorities for registration. We continue to be put at a significant competitive disadvantage in the industry because of EPA's resistance to issuing GLP certificates like every other OECD nation. Several times in the last few months we have lost projects to laboratories in s received the other countries because of this issue. Just this morning, our following email from a Chinese client. Dear Exy I am very sorry to tell you that we would not put the study of glyphosate ammonium in your lab. Because the Korea client tell us that the Korea Authority only accept the report with GLP certificate when evaluation. We decide to choose OECD GLP Lab. Thank you very much for your work. I hope we can cooperate next time. Yours sincerely. EX Market®istration Division I have been with Product Safety Labs for over 25 years and have grown incredibly frustrated over this issue. I would like to know if you could be available for a short discussion by phone so that I could understand the agencies position on this issue and discuss possible ways to address it. Best regards Field Code Changed

Exb = Exemption 6

- Repeated Dose Toxicology
 Reproductive/Developmental Toxicology
- Reproductive/Developmen
 Genetic Toxicology
 Environmental Toxicology
 Product Chemistry
 GLP Analytical Chemistry
 Antimicrobial Efficacy

Ex6 = Exemption 6

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From:		Ext	
Sent:		Monday, March 30, 2015 6:34 PM	
To:		EXA	
Cc:		Duffy, Rick;	***
Subject:	ex-	Request to GLP lab cortification and amail response for your review	
Attachments:		Labs email response 3-30.docx; etter and	W
		Response Why doesnt EPA issue GLP certificates to labs 3-18-15.docx	

HI GX6

A topic on the agenda for your weekly with Wednesday is "Request re GLP lab certification." The President of a lab emailed expressing concern about a competitive disadvantage. Jim forwarded the email to and asking Francis to respond. Attached is an email response for your review and the original email as background. The second attachment is a more detailed background paper for twhich again summarizes the incoming email from the lab, and explains the GLP program.

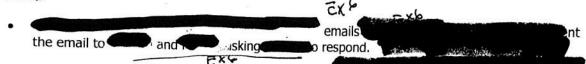


Ex6 = Exouption 6

Summary

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exb



- expressed feeling at a competitive disadvantage because EPA does not issue FIFRA Good Laboratory Practice certificates to laboratories like other Organization for Economic Cooperation and Development (OECD) countries.
- It's true, EPA is the only OECD country with a GLP program that does not issue sertificates to laboratories. The US GLP program is a quality management system used to validate studies and data generated and submitted as part of pesticide or chemical registration applications under FIFRA.
- Currently, neither FIFRA nor the Good Laboratory Practice Regulations authorize the issuance of certifications. The existing GLP inspection program constitutes a compliance monitoring and enforcement program to detect and deter violations of the GLP regulations and to assist in regulatory decision-making.
- The GLP Program is affected by EPA's membership in the GLS subscribes to the Mutual Acceptance of Data (MAD) program. The MAD program requires OECD members to accept data from each other for review. This program beliens the economy by making it easier for pesticide and chemical companies to engage in international trade. To be part of the MAD program, EPA must have a valid and active GLP Compliance Monitoring Program and conduct inspections. A certification program is not required.

Exc Draft Res	ponse to Incoming Email for review:		
Dear	ext		
	Ekr.	2×6	Ext
Your email to	has been forwarded to me for response. As	indicate	d in mail to
you,			
sommunitus and a	As such, I sincerely appreciate receiving fee		
community and re	cognize the issues and concerns raised in your email.	I understand	your frustration.

I want to assure you that EPA is not resisting the issuance of GLP certificates, as you indicate in your email. As currently written, neither the Federal Insecticide, Fungicide and Rodenticide Act nor the Good Laboratory Practice regulations authorize the EPA to certify GLP laboratories in the US. Instead, studies that are submitted to EPA in support of registration applications must be conducted in accordance with the GLP regulations. A change in this framework will require changing the regulations. The GLP program is based on existing statutory and regulatory authorities, which authorize a complete enitoring and enforcement program to detect and deter violations of the regulations and to assist in regulatory decision-making. EPA's inspection program is accepted by OECD and, therefore, we do participate in the Mutual Acceptance of Data program.

If you would like to discuss your concerns or if you have any questions about EPA's GLP program, a teleconference can be arranged.

Sincerely.

Exb = Exemption b



Background-Incoming email chain:

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From: Sent: Monday, March 16, 2015 2:51 PM To: Cc: Giles-AA, Cynthia Subject: RE: GLP Certification 2 X 6 I am forwarded your message to my colleague in the Office of Enforcement and Compliance Assurance, Assurance, CX 6 CX 6 CX 7 CX 7 CX 7 CX 8 CX 9 C	य अ
Sent: Monday, March 16, 2015 10:29 AM To: Subject: RE: GLP Certification	, 44 _{1,} 3
Ex6 I never heard back from you about this. Can we please schedule a time to speak this week?	

EXX From:

Sent: Saturday. February 28, 2015 6:55 AM

EXL Subject: GLP Certification

Ex 6

I manage a contract lab that specializes in the conduct of toxicology and chemistry studies on pesticides for submission to global regulatory authorities for registration. We continue to be put at a significant competitive disadvantage in the industry because of EPA's resistance to issuing GLP certificates like every other OECD nation. Several times in the last few months, we have lost projects to laboratories in other countries because of this issue. Just this morning, our Director of Analytical Services received the following email from a Chinese client.



Good day!

I am very sorry to tell you that we would not put the study of glyphosate ammonium in your lab. Because the Korea client tell us that the Korea Authority only accept the report with GLP certificate when evaluation. We decide to choose OECD GLP Lab. Thank you very much for your work. I hope we can cooperate next time.

Yours sincerely, FXF

Market®istration Division

I have been with Product Safety Labs for over 25 years and have grown incredibly frustrated over this issue. I would like to know if you could be available for a short discussion by phone so that I could understand the agencies position on this issue and discuss possible ways to address it.

Best regards



- Repeated Dose Toxicology
- Reproductive/Developmental Toxicology
- Genetic Toxicology - Environmental Toxicology
- Product Chemistry
- GLP Analytical Chemistry
- Antimicrobial Efficacy

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FIFRA GLP Laboratory Inspection Briefing for Cynthia Giles

Summary

- the email to Cynthia and GLP Section Chief. OECA's FIFRA GLP Section is within the Office of Compliance.
- expressed feeling at a competitive disadvantage because EPA does not issue FIFRA Good Laboratory Practice certificates to laboratories like other Organization for Economic Cooperation and Development (OECD) countries.
- It's true, EPA is the only OECD country with a GLP program that does not issue certificates to laboratories.
- Currently, neither FIFRA nor the Good Laboratory Practice Regulations authorize the issuance of certifications. The existing GLP inspection program constitutes a compliance monitoring and enforcement program to detect and deter violations of the GLP regulations and to assist in regulatory decision-making.
- The GLP Program is affected by EPA's membership in the OECD. As an OECD member, EPA subscribes to the Mutual Acceptance of Data (MAD) program. The MAD program requires OECD members to accept data from each other for review. This program benefits the United States economy by making it easier for pesticide and chemical companies to engage in international trade. To be part of the MAD program, EPA must have a valid and active GLP Compliance Monitoring Program and conduct inspections. A certification program is not required.

Background-Overview of the Current FIFRA GLP Program

EPA's GLP Program is a quality management system used to ensure the integrity and validity of scientific studies and data generated and submitted as part of pesticide or chemical registration applications under FIFRA. EPA does not test pesticides to support registrations. Rather, EPA relies on studies performed by or for applicants for registration. Laboratories are sometimes owned by the registrant but can also be independently operated and hired by the registrant. It is not required for the corrections must be certified, however, studies that are submitted to EPA in support of registration applications must be conducted in accordance with the GLP regulations, which requires laboratory personnel to have adequate education, training and experience to conduct the study.

The GLP regulation, 40 CFR Part 160, covers a wide variety of areas including equipment maintenance and calibration, testing operations, test substances, study protocols, the conduct of a study, recordkeeping and reporting requirements as well as testing facility management. An important feature of the GLP regulation is the Statement of compliance or non-compliance. 40 CFR 160.12. Any person who submits an application to EPA for a research or marketing permit that contains a study must submit a true and correct statement, signed by the applicant, the sponsor of the study and the study director. The statement must contain one of three listed assertions: (1) whether the statement must contain one of three listed assertions:

accordance with GLP rule or (2) all the differences between the practices used in the study and those required by the GLP rule or (3) the signatory was not a sponsor or the study, did not conduct the study and does not know whether the study was conducted in accordance with the GLP rule.

An NAIS inspection will include an on-site facility compliance as a data audit. A data audit is where a study is selected and reviewed by the inspector to verify that the data from the study is consistent with the final report that was submitted to EPA. The NAIS uses a random selection process or the Laboratory Information and Study Audit (LISA) database that screens for the following neutral criteria:

- Labs that have submitted the most number of studies to EPA in the last 3 years,
- Labs that had major GLP findings in a previous inspection,
- Labs that have initiated testing under FIFRA or TSCA for the first time,
- Labs that have submitted a study that is expected to form the basis for a major regulatory action,
- Labs that have not been inspected for the last 3 years,
- Labs located in geographic proximity to other laboratories.

Currently, the only sections of FIFRA that would address violations of the GLP regulations is FIFRA Section 12(a)(2)(M)(Q) and (R). All are based on submissions to the Agency. The most common enforcement action concerns the submission of a false 160.12 compliance statement where the submitter attests that a study was conducted in accordance with GLP regulations, but deviations were found during the inspections. If this statement is false, a civil or criminal enforcement response may be pursued by the Agency. There are no other bases for initiating an enforcement action for a violation of the GLP regulations. In the case of missing raw data, an enforcement action can be initiated for violating 40 CFR Part 169. GLP violations can result in the rejection of a study by EPA and, therefore, a denial of a registration application.

Incoming Communication:

EXF

From: Sent: Saturday, February 28, 2015 6:55 AM

Subject: GLP Certification

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EX6

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arket & Registration Division EXB

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